

FEB 18 2000

K000156

**APPENDIX H****510(k) SUMMARY**

**SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR  
SMART SHIELD POWDER FREE PEPPERMINT SCENTED GREEN  
LATEX EXAMINATION GLOVES WITH A PROTEIN CONTENT LABELING**

**Contact person :** Ong Lay Mau

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

**Device Information:**

Trade Name - SMART SHIELD POWDER FREE PEPPERMINT SCENTED GREEN LATEX EXAM GLOVES

Common Name - Exam gloves

Classification Name - Patient examination glove (per 21 CFR 880.6250)

Classification Information - Class I latex patient examination glove 80LYY, powder free and meeting all the requirements of ASTM-D3578-99 Standard Specification for Latex Examination Gloves for Medical Application.

**Device Description:**

Class I latex patient examination gloves 80LYY, powder free and meeting all the requirements of ASTM-D3578-99 Standard Specification for Latex Examination Gloves for Medical Application.

**Intended Use of Device:**

A medical glove to be worn on the hand of the health care and similar personnel to prevent contamination between health care personnel and patient.

Technological Characteristics of Device:

**1. Dimension**

DIMENSION	ASTM D3578-99	SMART SHIELD
X-Small	70 mm +/- 10 mm	70 - 75 mm
Small	80 mm +/- 10mm	80 - 85 mm
Medium	95 mm +/- 10mm	90 - 97 mm
Large	111mm +/- 10mm	105 - 111 mm
Length	230 mm minimum for all sizes	242mm
Thickness - Finger Palm	0.08mm min 0.08mm min	0.08 mm min 0.08 mm min

## 2. Physical Properties (ASTM-D3578-99 Standard Specification for Latex Exam Gloves)

	TENSILE STRENGTH		ULTIMATE ELONGATION	
	ASTM-D3578-99	SHIELD's	ASTM-D3578-99	SHIELD's
Before Aging	14.0 Mpa min	21.0 Mpa	700 %	800%
After Aging 22 hrs @100C	14.0 Mpa min	16.0 Mpa	500%	750%

## 3. Water Tight Test

Using the FDA specified 1,000 ml water leak test, 200 pieces of each size of the gloves were tested and our results are as given below:

CONSIGMENT #	SIZE	SAMPLE SIZE	LEAK STATUS	NUMBER LEAKED
3370/3371	X-Small	200	Yes	3
3370/3371	Small	200	Yes	3
3370/3371	Medium	200	Yes	4
3370/3371	Large	200	Yes	3

The above figures are within the FDA/ ASTM requirements for latex exam gloves of 2.5% AQL.

## 4. Biocompatibility

The test results below show that the gloves meet FDA biocompatibility requirements:

### BIOCOMPATIBILITY TESTS

Primary Dermal Irritation Test

Skin Sensitization Study

### RESULTS

Not a primary irritant

Not a sensitizer

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**5. Total Residual Powder Content & Presence of Cornstarch**

TESTS	FDA INTERNAL REQUIREMENT	SHIELD's
Residual Powder Content per ASTM D 6124-97	2 mg/glove max	Range: 1.2-1.7mg/glove Mean : 1.5 mg/glove
Presence of Cornstarch	Negative	Negative

**6. Residual Protein Level**

TESTS	FDA ALLOWABLE LEVEL	CLAIMED LEVEL
ASTM D 5712-95	< 50 µg/g	< 50 µg/g Range: 26-34 Mean: 31

**Conclusion:-**

The data presented indicate that the Royal Shield Powder Free Peppermint Scented Green latex examination glove with a protein labeling claim qualifies to be labeled as such since it

1. meets/exceeds ASTM- D3578-99 Standard Specifications For Latex Examination Glove,
2. meets FDA pinhole requirements,
3. meets SHIELD's labeling claim of its being a powder free glove.
4. meets the protein labeling claim level at <50 µg/g



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**FEB 18 2000**

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Shield Gloves Manufacturer (M) SDN BHD  
c/o Ms. Janna P. Tucker  
Official Correspondent  
Tucker and Associates  
198 Avenue De La D'emerald  
Sparks, Nevada 89434-9550

Re: K000156  
Trade Name: Smart Shield Powder Free Latex Examination  
Gloves Green, Peppermint Scented, Contains 50 Mcgm or  
Less of Total Water Extractable Protein Per Gram  
Regulatory Class: I  
Product Code: LYY  
Dated: January 14, 2000  
Received: January 19, 2000

Dear Ms. Tucker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP

regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

Applicant: Shield Gloves Manufacturer (M) Sdn Bhd.

510K Number: K000156

Device Name: Smart Shield Powder Free Latex Examination Gloves Green, Peppermint Scented, contains 50mg or less of total cedar extract protein per gram.

Indications For Use:

This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.

.....  
Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use .....  
Per 21 CFR 801.109

OR

Over-The-Counter... ☒ .....

SKB for Chen  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K000156